DENTAMERICA

K060640

510(k) Summary

APR 2 4 2006

Submission Date: February 20, 2006

Submitter's Information:
Dentamerica Inc.®
18320 Bedford Circle
Industry, CA 91744

Contact Person: Eric Huang, (Product Manager)
Phone: 626-912-1388
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Establishment Registration Number: 2024949

Trade Name: Digirex™
Common Name: Digital Dental Radiography System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: 90 EHD

Performance Standard: None established under section 514
Reason for 510(k): New finished device
Special controls: No applicable mandatory performance standards or special controls exist for this device.

Substantially Equivalent Legally Marketed Devices (predicates):

RSV (Radiology System Visiodent) Device – K031448
EVA Digital Dental X-Ray System – K030647
Visualix Radiographic Image Detecting and Process – K925094

Intended Use and Device Description:

The Digirex™ Digital Dental Radiography System replaces the traditional film approach to x-ray imaging. A digital sensor rather than film is used to capture x-rays from an external source and produce digital images of a patient's mouth. The digital sensor and the USB controller allow the images to be transferred to a computer for analysis, archiving and electronic transmission.

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Technological Characteristics and Substantial Equivalence:

The Digirex™ Digital Dental Radiography System has a number of substantially equivalent (SE) predicate devices. These predicate devices use the same technological methods to perform the task of digital image capture from an external x-ray source. A digital sensor and USB controller are the main components of the predicate devices.

Digital dental radiography eliminates the need for conventional film to produce images from an external x-ray source. The benefits of this are two-fold. First, images appear instantaneously. There is no longer a need for a dark room and chemicals to process the undeveloped x-ray film. Second, and more importantly, is that a much smaller dose of x-ray radiation is required to produce an image, benefiting the patient.

P.O. Box 3200, Industry, California 91744, U.S.A. • Tel: (626) 912-1388 • Fax: (626) 913-0510

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 2 4 2006

Mr. Eric Huang
Product Manager
Dentamerica, Inc.
18320 Bedford Circle
INDUSTRY CA 91744

Re: K060640
Trade/Device Name: Digirex™ Digital Dental Radiography System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: February 20, 2006
Received: March 10, 2006

Dear Mr. Huang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060640

Device Name: Digirex™ Digital Dental Radiography System

Indications for Use:

The Digirex™ Digital Dental Radiography System replaces the traditional film approach to x-ray imaging. A digital sensor rather than film is used to capture x-rays from an external source and produce digital images of a patient's mouth. The digital sensor and the USB controller allow the images to be transferred to a computer for analysis, archiving and electronic transmission.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ AND/OR Over-the Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060640